510(k) SUMMARY

FEB 10 2014

Submitter Information

Address:	Interventional Spine, Inc. 13600 Alton Parkway, Ste. 160 Irvine, CA 92618
Telephone:	(949) 472-0006
Contact Person:	Jane Metcalf
Date prepared:	November 19, 2013

Name of Device

Trade name:	Opticage™ Expandable Interbody Fusion Device, Model Series 9070
Common name:	Intervertebral Body Fusion Device
Classification:	Class II (Special Controls) per 21 CFR 888.3080
Product Code:	MAX

Purpose of Submission

The purpose of this submission is to gain market clearance for additional sizes of implants utilizing the technology of the Opticage Expandable Interbody Fusion Device, Model Series 9070.

Substantially Equivalent To

The additional sizes described in this submission are substantially equivalent to the Opticage Expandable Interbody Fusion Device, Model Series 9070, cleared under K113527 and K132479.

Description of the Device Subject to Premarket Notification

The Opticage Expandable Interbody Fusion Device, Model Series 9070 is composed of lumbar intervertebral body fusion implants manufactured from implant grade titanium alloy and ranging in widths from 9 mm x 12 mm and lengths from 21 x 30 mm. Each implant consists of an upper and lower titanium plate and two titanium wedges that interact to change the height of the construct from a minimum of 9 mm to a maximum of 14 mm. The top and bottom plates are fenestrated and contain a window to enhance bony in-growth. A cavity internal to the device is intended to hold autogenous bone graft.

510(k) SUMMARY (continued)

Indication for Use

The Opticage Interbody Fusion Device is a posterior lumbar intervertebral body fusion device and is indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). The Opticage Interbody Fusion Device can be implanted via posterior or transforaminal approach.

DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. Candidates for surgery should be skeletally mature and have had six months of conservative treatment. These patients may have had primary or secondary surgery, but no previous fusion at the involved levels.

The device is not intended to be used as a stand-alone device. It must be used with supplemental internal spinal fixation systems that have been cleared for use in the lumbar spine (i.e. facet screw fixation systems, facet compression devices and posterior pedicle screw and rod systems).

Technical Characteristics

The Opticage Expandable Interbody Fusion Device, Model Series 9070 is designed to hold bone graft, to be expanded after implantation, and to allow bony ingrowth through-out the device. Expansion of the device is accomplished by rotating a central shaft that moves the side wedges inward, increasing the distance between the top and bottom plates.

Performance Data

All necessary performance testing was completed for the previously cleared Opticage Expandable Interbody Fusion Devices in Model Series 9070. A Finite Element Analysis (FEA) model was developed and validated to show that the additional sizes perform at least equivalently to the previously cleared devices.

Basis for Determination of Substantial Equivalence

The additional sizes of the Opticage Expandable Interbody Fusion Device, Model Series 9070, are determined to be substantially equivalent to the Opticage Expandable Interbody Fusion Devices from Model Series 9070, previously cleared under K113527 and K132479 based on comparisons to device design, indications for use, technological characteristics, and FEA analysis.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 10, 2014

Interventional Spine, Incorporated
Ms. Jane Metcalf
Vice President, Quality Assurance, Regulatory and Clinical Affairs
13700 Alton Parkway, Suite 160
Irvine, California 92618

Re: K133583
Trade/Device Name: Opticage™ Expandable Interbody Fusion Device, Model Series 9070
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: January 11, 2014
Received: January 13, 2014

Dear Ms. Metcalf

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Vincent J. Devlin -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K133583

Device Name
Opticage(TM) Expandable Interbody Fusion Device, Model Series 9070

Indications for Use *(Describe)*
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Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Anton E. Dmitriev, PhD
FDA
Division of Orthopedic Devices

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